UNITED STATES DISTRICT COURT
DISTRICT OF NEBRASKA

Stephanie Ideus,

Civil File: 4:16-cv-03086-JMG-CRZ

Plaintiff,

v.

Teva Pharmaceuticals USA, Inc. and Teva Women's Health, Inc.,

Defendants.

DEFENDANTS TEVA PHARMACEUTICALS USA, INC., AND TEVA WOMEN'S HEALTH, INC.'S MOTION FOR JUDGMENT ON THE PLEADINGS

Defendants Teva Pharmaceuticals USA, Inc., and Teva Women's Health, Inc., move pursuant to Rule 12(c) of the Federal Rules of Civil Procedure for dismissal of plaintiff's claims. This motion is supported by the accompanying memorandum of law.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing has been served, via the Court's ECF system, this 10th day of July, 2017, upon:

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MEMORANDUM IN SUPPORT OF DEFENDANTS TEVA PHARMACEUTICALS USA, INC., AND TEVA WOMEN'S HEALTH, INC.'S MOTION FOR JUDGMENT ON THE PLEADINGS

I. INTRODUCTION

Plaintiff's Amended Complaint and Jury Demand ("Complaint") names Teva Pharmaceuticals USA, Inc., and Teva Women's Health, Inc. as defendants. Plaintiff complains that she was injured as a result of some unidentified defect in the prescription product, ParaGard® T380A Intrauterine Copper Contraceptive, plaintiff had placed for birth control. (*See generally* Complaint.) Plaintiff does not, however, state an actionable claim against defendants. Plaintiff alleges that the ParaGard® broke and an arm of the ParaGard® remained embedded in the myometrium of her uterine wall, but she does not allege any facts to state a viable claim. The Complaint includes causes of action captioned as negligence, strict products liability, breach of express warranty, fraudulent misrepresentation, and negligent misrepresentation, each of which centers on vague allegations of inadequate warnings.

Taken as a whole, plaintiff's Complaint, at best, alleges only claims based on an asserted failure to warn. The Rule 26(f) Report (Doc. 19) bears out that conclusion. Under the causes of action in the Rule 26(f) Report, plaintiff's "factual application" refers to breakage, migration,

and or embedment of the ParaGard® and defendants' purported failure to provide sufficient warnings of those potential "risks," (Rule 26(f) Report, II. 1) & 2, Doc. 19)), or alternately that defendants purportedly stated the product was fit for its intended purpose (*Id.*, II. 3), 4), & 5), Doc. 19.) There is only one oblique reference to any cause of action other than one based on inadequate warnings: "The product may also have been defectively manufactured." (*Id.*, II, 2), Doc. 19.)

Notwithstanding plaintiff's specific statements in the Rule 26(f) Report, plaintiff's counsel referred to manufacturing defect and design defect causes of action in conjunction with certain discovery plaintiff seeks. While plaintiff's negligence and strict liability causes of action include vague references to an alleged defect in the ParaGard® design, (*see, e.g.,* Complaint, ¶28(k) (alleging defendants "[n]egligently design[ed] ParaGard in a manner which was dangerous to its users"); ¶31(a) (alleging defendants "[f]ailed to use due care in designing … ParaGard"); ¶41 (alleging ParaGard® "was defective in design")), those references invariably are coupled with references to inadequate warnings. Furthermore, nowhere in plaintiff's Complaint does she identify the nature of any alleged design defect or how that alleged defect caused any injury. (*See generally* Complaint.) The same is true of allegations of a manufacturing defect in plaintiff's ParaGard®. (*See id.*, ¶28(l) (alleging defendants "[n]egligently manufactur[ed] ParaGard in a manner which was dangerous to its users"); ¶31(a) (alleging defendants "[f]ailed to use due care in manufacturing … ParaGard"); ¶49 (alleging ParaGard® "was manufactured defectively").) Again, there are no factual allegations of any manufacturing defect in plaintiff's ParaGard®.

Aside from the complete failure to properly plead her claims (including her failure to plead fraud with the requisite specificity), any claim that ParaGard® is defectively designed, no

matter how plaintiff eventually might attempt to describe that defect should she ever identify it, the claim is preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA") as explained by the United States Supreme Court in *Mutual Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. 2466 (2013). "Once a drug – whether generic or brand-name – is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application." *Id.* at 2471. A design defect claim would require defendants to redesign their product to avoid liability under state law. That is precisely the kind of impossibility that led the Supreme Court to find the design defect claim alleged in *Bartlett* preempted. As the Court definitively stated in *Bartlett*, "we hold that state-law design defect claims … that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling." *Id.*

Likewise, any claim premised on a failure to warn is preempted by federal law. Following the trilogy of United States Supreme Court cases addressing federal preemption of state-law claims involving pharmaceutical products, it is clear that pharmaceutical manufacturers of drugs approved under a new drug application cannot change their product label without FDA's approval unless newly acquired information scientifically supports a unilateral change to the product label. Plaintiff does not identify any information, much less newly acquired information, that would have enabled defendants to revise ParaGard®'s labeling after September 1, 2005 (the last time the content of the labeling was revised after extensive FDA review) and before 2010 when plaintiff's ParaGard® was placed.

As a result, defendants are entitled to judgment as a matter of law.

II. STATEMENT OF FACTS

A. PLAINTIFF'S ALLEGATIONS

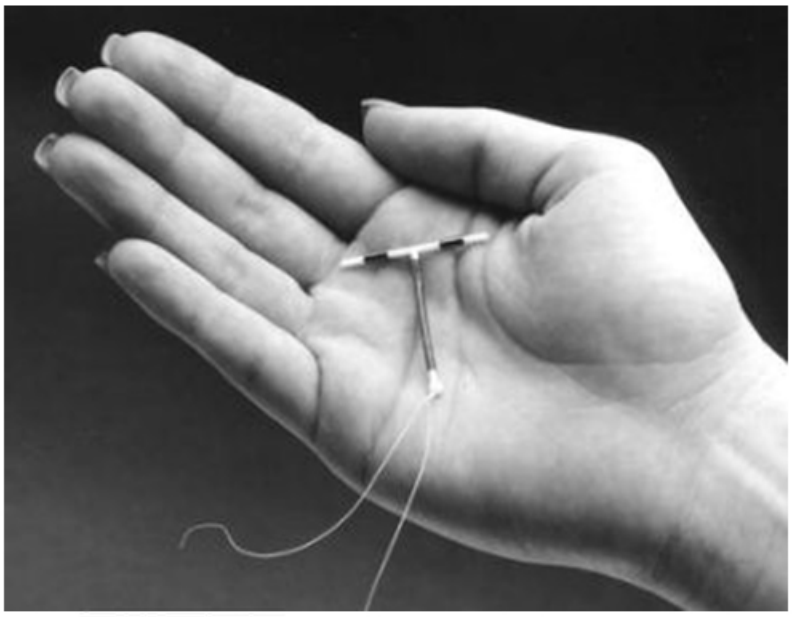
Plaintiff alleges that the ParaGard® she had placed on January 11, 2010, for contraception, was removed in July 2014. (Amended Complaint, ¶¶10, 11.) Upon removal, an arm of the ParaGard® remained embedded in the myometrium of her uterus wall. (*Id.*, ¶¶11, 13.) After an ultrasound was performed, the embedded arm was removed surgically in February 2015. (*Id.*, ¶13.)

Plaintiff's amended complaint is rife with conclusory, vague allegations of risks, defects, and the absence of unspecified information. (*See generally, id.*) For instance, plaintiff alleges that in marketing efforts defendants "overstate[d] the benefits of ParaGard, and minimize[d] the risks associated with ParaGard." (*Id.*, ¶15.) She does not, however, specify what "risks" allegedly were minimized. Similarly, she alleges that defendants "fraudulently withheld important safety information from physicians and the public," (*id.*), but does not identify what "safety information" was withheld. The most specific allegation plaintiff makes is that "no warning that the ParaGard may break was given in the warning [or adverse event] section." (*Id.*, ¶¶20, 21.) She concludes that her use of ParaGard® caused her to "suffer[] from having a broken arm of the ParaGard in her, causing her damage …." (*Id.*, ¶24.)

B. PARAGARD®, ITS APPROVAL HISTORY AND LABELING

ParaGard® is a copper "T" shaped intrauterine device ("IUD") placed in the uterus to prevent pregnancy. The T-frame is made of polyethylene plastic. Approximately 176 mg of copper wire is coiled along the vertical stem and a 68.7 mg collar on each horizontal arm. A ParaGard® measures 32 mm horizontally and 36 mm vertically. (ParaGard® package insert,

available at FDA's website at Drugs@FDA.[1]) A ParaGard® is pictured below.



The new drug application ("NDA") for ParaGard® was approved by the federal Food and Drug Administration ("FDA") on November 15, 1984. (*See* ParaGard® Approval History, available at FDA's website at Drugs@FDA.)

ParaGard®'s labeling includes a package insert with prescribing information for the physician titled "PRESCRIBING INFORMATION," including detailed diagrams on the proper placement of the IUD, and a patient package insert titled "INFORMATION FOR PATIENTS." (ParaGard® package insert.) In addition to a product description, the Prescribing Information describes the mode of action for contraception, indications and usage, instructions for use, and information for patients. The Prescribing Information also includes warnings, contraindications, precautions, and potential adverse reactions to ParaGard®. Under "Warnings," the prescribing

[1] The ParaGard® package insert is available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/018680s060lbl.pdf. The Court may take judicial notice of the ParaGard® package insert as it is a public record. *See Redd v. DePuy Orthopaedics, Inc.*, 48 F. Supp. 3d 1261, 1266 n.4 (E.D. Mo. 2014) (noting court may take judicial notice of public records on a motion to dismiss (citing *Stahl v. U.S. Dept. of Agriculture*, 327 F.3d 697, 700 (8th Cir. 2003).

information lists "embedment" and "perforation":

> 5. **Embedment**
> Partial penetration or embedment of ParaGard® in the myometrium can make removal difficult. In some cases, surgical removal may be necessary.
> 6. **Perforation**
> Partial or total perforation of the uterine wall or cervix may occur rarely during placement, although it may not be detected until later. Spontaneous migration has also been reported. If perforation does occur, remove ParaGard® promptly, since the copper can lead to intraperitoneal adhesions. Intestinal penetration, intestinal obstruction, and/or damage to adjacent organs may result if an IUD is left in the peritoneal cavity. Pre-operative imaging followed by laparoscopy or laparotomy is often required to remove an IUD from the peritoneal cavity.

(*Id.*) Similarly, "Perforation" and "Embedment" are disclosed among the "most serious adverse events associated with intrauterine contraception" under the Adverse Reactions section of the package insert. (*Id.*) Under "Continuing Care," the physician is advised that "ParaGard® can break" and that it can "perforate the uterus." (*Id.*) In the section of the package insert titled "How to Remove ParaGard®," the physician again is advised of the risks of embedment and/or breakage:

> Embedment or breakage of ParaGard® in the myometrium can make removal difficult. Analgesia, paracervical anesthesia, and cervical dilation may assist in removing an embedded ParaGard®. An alligator forceps or other grasping instrument may be helpful. Hysteroscopy may also be helpful.

(*Id.*)

Finally, under "Precautions," in a section titled "Information for Patients," the prescribing physician is advised as follows:

> Before inserting ParaGard® discuss the Patient Package Insert with the patient, give her time to read the information. Discuss any questions she may have concerning ParaGard® as well as other methods of contraception. Instruct her to promptly report symptoms of infection, pregnancy, or missing strings.

(*Id.*) In turn, the "Information for Patients" advises under a section titled "What side effects can I expect with ParaGard®," that there can be "[d]ifficult removals" and "[o]ccasionally

ParaGard® may be hard to remove because it is stuck in the uterus. Surgery may sometimes be needed to remove ParaGard.®." (ParaGard® information for patients.) It also advises:

> Perforation: Rarely, ParaGard® goes through the wall of the uterus, especially during placement. This is called perforation. If ParaGard® perforates the uterus, it should be removed. Surgery may be needed. Perforation can cause infection, scarring, or damage to other organs. If ParaGard® perforates the uterus, you are not protected from pregnancy.

(*Id.*)

The labeling that was in effect at the time of plaintiff's placement in 2010 was approved by FDA on September 1, 2005. (*See* ParaGard®'s Approval History at Drugs@FDA.)

III. LAW AND ARGUMENT

A. STANDARD OF REVIEW

A motion for judgment on the pleadings must be granted where there is no material issue of fact thereby entitling the moving party to judgment as a matter of law. *See Waldron v. Boeing Co.*, 388 F.3d 591, 593 (8th Cir. 2004). The same standard used in considering a Rule 12(b)(6) motion to dismiss for failure to state a claim is applied in evaluating a motion for judgment on the pleadings. *See Clemons v. Crawford*, 585 F.3d 1119, 1124 (8th Cir. 2009). While the court, in considering the motion, assumes the facts alleged in the complaint are true and construes all reasonable inferences from those facts in plaintiff's favor, the court need not accept as true wholly conclusory allegations or legal conclusions that the plaintiff draws from the facts pled. *See Hanten v. Sch. Dist. Of Riverview Gardens*, 183 F.3d 799, 805 (8th Cir. 1999); *Westcott v. City of Omaha*, 901 F.2d 1486, 1488 (8th Cir. 1990).

For the plaintiff to survive a motion to dismiss, the complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007). Mere "labels and conclusions" are insufficient. *Id.* at 555. "A claim has facial

plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). "Plausibility" requires more than a "sheer possibility that a defendant has acted unlawfully" or the "mere possibility of misconduct," and a complaint that alleges facts that are "merely consistent with" liability "stops short of the line between possibility and plausibility of 'entitlement to relief.'" *Iqbal*, 556 U.S. at 678-79 (citing *Twombly*, 550 U.S. at 557). The well-pled allegations in a complaint must "nudge[] [a party's] claims across the line from conceivable to plausible." *Twombly*, 555 U.S. at 570.

In *Twombly*, the Supreme Court recognized the liberal minimal standards imposed by Civil Rule 8(a)(2), which requires the plaintiff to state "a short and plain statement of the claim showing that the pleader is entitled to relief," but ruled that a plaintiff's complaint must contain facts with enough specificity "to raise a right to relief above the speculative level." *Id*. at 555. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements," will not pass muster under *Twombly*. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (*citing Twombly*, 550 U.S. at 555).

When considering a motion for judgment on the pleadings, materials outside the pleadings generally are ignored. The Court, however, may consider "some materials that are part of the public record or do not contradict the complaint," orders, materials embraced by the complaint, and exhibits attached to the complaint. *Porous Media Corp. v. Pall Corp*., 186 F.3d 1077, 1079 (8th Cir. 1999). *See also Dittemore v. Transit Auth. of the City of Omaha*, No. 8:16-CV-23, 2016 WL 3945154, at *2 (D. Neb. July 19, 2016) ("On a motion to dismiss, in addition to the pleadings, the Court may also consider some information which is not contained within the

complaint, such as materials that are part of the public record and materials that are necessarily embraced by the pleadings, without transforming the motion into one for summary judgment.").

B. PLAINTIFF'S COMPLAINT DOES NOT ALLEGE FACTS TO STATE A CLAIM FOR RELIEF PLAUSIBLE ON ITS FACE

The crux of plaintiff's claims is that the ParaGard® she had placed for birth control broke. (*See generally* Complaint.) While, as plaintiff admits, the potential that a ParaGard® IUD can break is included in the product labeling, plaintiff complains there was no warning of breakage in the "warnings section" (Complaint, ¶20), or the "adverse event section" (*id.*, ¶21); and that there was no warning the ParaGard® could be broken if the threads were visible (*id.*, ¶¶22, 23). Aside from that, plaintiff's Complaint is a study in vague, conclusory statements and legal conclusions – none of which state a viable claim sufficient to withstand scrutiny. Plaintiff's Complaint simply does not plead facts to state a claim that is plausible on its face.

Plaintiff asserts five causes of action – negligence, strict products liability, breach of express warranty, fraudulent misrepresentation, and negligent misrepresentation. (*See generally* Complaint.) The allegations under each cause of action, however, are no more than a recitation of the elements for that claim. And, the factual allegations that are included in plaintiff's Complaint shed no light whatsoever on the nature of her claims.

While the best one might glean from plaintiff's allegations is that she believes ParaGard® is accompanied by inadequate warnings, her counsel recently declared plaintiff was pursuing design defect and manufacturing defect claims. Nowhere in her Complaint, however, does plaintiff identify any defect in ParaGard®'s design, nor any facts that her ParaGard® was not manufactured in accordance with the product's specifications. Instead, plaintiff relies on declaratory statements. Her negligence cause of action exemplifies the deficiencies in plaintiff's allegations.

Under that cause of action, plaintiff makes mere declarations of duty and failure to exercise ordinary care:

- "Defendants had a duty to exercise reasonable care in designing, researching, manufacturing …." (Complaint, ¶26.)
- "Defendants failed to exercise ordinary care in designing, researching, manufacturing …." (*Id.*, ¶27.)

The purported acts or omissions she alleges constitute negligence are likewise mere vague, conclusory statements:

- Defendants did not thoroughly or adequately test. (Complaint, ¶28(a)-(d), (g).)
- Defendants failed to adequately and correctly warn "of the dangers of ParaGard" and failed to provide adequate instructions. (*Id.*, ¶28(e)-(f).)
- Defendants recommended ParaGard® "without sufficient knowledge as to its dangerous propensities." (*Id.*, ¶28(h).)
- Defendants represented ParaGard® was safe for its intended use and as safe and efficacious as other forms of birth control. (*Id.*, ¶28(i)-(j).)
- Defendants negligently designed, manufactured, produced, and assembled ParaGard®. (*Id.*, ¶28(k)-(n).)
- Defendants concealed and misrepresented information that ParaGard® was "unsafe [and] dangerous," and concerning "the severity of risks and dangers of ParaGard compared to other forms of birth control." (*Id.*, ¶28(o)-(p).)

Noticeably absent from plaintiff's allegations are any facts of the "testing" necessary or omitted, the "dangers" or "risks" purportedly withheld, or the nature of the design or manufacturing defects. Nor are there allegations as to how any unpled, unidentified defect caused plaintiff injury, which, of course, is necessary to plead a submissible case. *See Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1138 (8th Cir. 2014) (citing *Winter v. Novartis Pharm. Corp.*, 739 F.3d 405, 408 (8th Cir. 2014)). The allegations in her other causes of action follow the same format – a recital of the elements of the cause of action and conclusory declarations without supporting facts. That is not enough to state a claim that is plausible on its face.

As the Supreme Court stated in *Iqbal*, "[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. Here, plaintiff's Complaint is devoid of "factual content." The sum total of the factual content of plaintiff's allegations is that she had a ParaGard® placed (Complaint, ¶10); she had it removed (*id.*, ¶11); the ParaGard® broke (*id.*); an arm of the ParaGard® was embedded in the myometrium of her uterine wall, which she had surgically removed (*id.*, ¶¶12-13); the ParaGard® label warned of embedment, perforation, and breakage (*id.*, ¶¶20, 21, 22, 23).

The Supreme Court made clear in *Iqbal* and *Twombly* that more than "unadorned, the defendant-unlawfully-harmed me accusation[s]" are required to state a viable, plausible claim. *Iqbal*, 556 at 678. Instead, plaintiff must make a "showing" rather than a blanket assertion that she is entitled to relief from defendants. *Twombly*, 550 U.S. at 444, n.3. Because plaintiff's allegations against defendants are merely conclusory, they are not entitled to a presumption of truth and judgment should be entered for defendants on each and every cause of action. *See Iqbal*, 556 U.S. at 678.

C. DESIGN DEFECT AND FAILURE-TO-WARN CLAIMS DIRECTED AT PHARMACEUTICAL PRODUCTS ARE PREEMPTED BY FEDERAL LAW

Aside from the fact that plaintiff does not state actionable claims against defendants, plaintiff's claims are preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA") which governs pharmaceutical products.

1. Federal Regulation of Pharmaceutical Products

a. New Drug Approval Process

Prescription drugs are regulated under the FDCA, which is implemented and enforced by FDA. *See* 21 U.S.C. §§301 *et seq*.; *id*., §§371, 393. A drug may not be marketed in interstate

commerce unless an application pursuant to 21 U.S.C. §355 is "effective"; i.e., has been approved by FDA. *See* 21 U.S.C. §355(a). Section 355(b) applies to new drugs, like ParaGard®, and requires submission of a new drug application ("NDA"). In reviewing an NDA, FDA physicians, chemists, statisticians, microbiologists, pharmacologists, and other experts scrutinize all aspects of the drug "from the design of clinical trials to the severity of side effects to the conditions under which the drug is manufactured." *See* FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective. FDA also may consult the sponsor and independent scientific experts. *See* 21 U.S.C. §355(n). NDA applicants must demonstrate the new drug is safe and effective for the proposed use before approval is granted. *See* 21 U.S.C. §355(b)(1)(A). Determinations of safety and efficacy are inextricably intertwined with the drug's use under the conditions set forth in the proposed labeling, which "serves as the standard under which FDA determines whether a product is safe and effective." *New Drug and Antibiotic Regulations – Final Rule*, 50 Fed. Reg. 7470 (Feb. 22, 1985); 21 U.S.C. §355(b)(1)(F).

b. Labeling Requirements for New Drugs

"Labeling" includes "all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. §321(m). "Label" is defined as "a display of written, printed, or graphic matter upon the immediate container of any article...." 21 U.S.C. §321(k); *see also* 21 C.F.R. §1.3. FDA's regulations govern the content and format of drug labeling. *See* 21 C.F.R. §§201.56 (general requirements), 201.57 (specific requirements). The title and content of each section required to appear in drug labeling is specified in FDA's regulations.

c. The Post-Approval Process and Labeling Changes

No provision in the FDCA permits a manufacturer to change an approved drug's labeling without prior FDA approval. *See* 21 U.S.C. §301 et seq. The FDCA prohibits introduction into interstate commerce of any drug not approved under §355. 21 U.S.C. §355(a). Any unapproved label change renders the drug a new, unapproved drug under the FDCA subject to the misbranding provisions. *See id*. Accordingly, under the FDCA, any change to an approved application must be approved by FDA prior to its implementation.

Despite that requirement, FDA issued a notice advising industry that it would exercise its discretion and not take enforcement action if NDA holders instituted labeling changes before approval: (i) to add or strengthen a contraindication, warning, precaution, or adverse reaction; (ii) to add or strengthen a statement about drug abuse, dependence, or overdosage; (iii) to add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product; or (iv) to delete unsupported indications for use or claims of effectiveness. *See* 21 C.F.R. §314.70(c); *Supplemental New-Drug Applications*, 30 Fed. Reg. 993, 993-94 (Jan. 30, 1965). Those changes are made using FDA's "changes being effected" ("CBE") procedure and must be based on "newly discovered safety information" and "sufficient evidence of a causal association with the drug." *See* 21 C.F.R. §314.70(c)(6)(iii)(A); *Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices – Proposed Rule*, 73 Fed. Reg. 2848, 2849 (Jan. 16. 2008). CBE supplements must include the "newly discovered safety information" supporting the change and must be submitted to FDA for ultimate approval. *See* 21 C.F.R. §314.70(c)(7). FDA can accept, modify, or reject a CBE supplement. *Id*. Outside the limited enumerated circumstances for which a CBE may be submitted, all other changes must be implemented through a prior approval supplement ("PAS").

2. The Supremacy Clause, *Wyeth v. Levine*, *PLIVA, Inc. v. Mensing*, and *Mutual Pharm. Co., Inc. v. Bartlett*

The United States Constitution provides that the laws of the United States "shall be the supreme Law of the Land; …any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. It has been well-settled since *M'Culloch v. Maryland*, 17 U.S. (4 Wheat) 316 (1819), that state law that conflicts with federal law is "without effect." *See Maryland v. Louisiana*, 451 U.S. 725, 746 (1981).

In recent years, the United States Supreme Court addressed preemption in lawsuits aimed at pharmaceutical products on three occasions. The first, *Wyeth v. Levine*, 555 U.S. 555 (2009), involved preemption of state-law claims involving pharmaceutical products approved through an NDA. The Court, pointing to FDA's CBE process, held it was not impossible for Wyeth to satisfy both its state law duty to provide adequate warnings and its duties under federal law. It did so, however, only because information existed that would have supported the submission of a CBE; i.e., newly acquired information existed that warranted a change to one or more of the label sections specified in 21 C.F.R. §314.70(c)(6). The Court acknowledged, however, that ultimately FDA must approve the change and FDA retains authority to reject the change. *Id*. Although the Court held that the plaintiff's claims in *Levine* were not preempted, it ruled that claims against an NDA holder are preempted where "clear evidence" shows FDA would not have approved a change to the drug's label, rendering it impossible for the manufacturer to comply with both state and federal law. *Id*. at 571-72.

Two years later, the Supreme Court again addressed preemption of claims against pharmaceutical manufacturers in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011). In that case, the Court addressed claims involving generic drugs approved under an abbreviated new drug application ("ANDA"). While the Court in *Mensing* acknowledged that the federal requirements applicable to NDA drugs differ from those applicable to ANDA, the Court was clear that the

"question for 'impossibility' preemption is whether the private party could *independently* do under federal law what state law requires of it." *Id*. at 620 (emphasis added) (*citing Levine*, 555 U.S. at 573). If not, the state-law is preempted.

Two years after *Mensing*, the Supreme Court decided *Mutual Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. 2466 (2013). In *Bartlett*, the Court reiterated its holding in *Mensing* and also held that state-law design defect claims aimed at pharmaceutical products are preempted. With respect to the design defect claim, the Court found that "[i]n the drug context, either increasing the "usefulness" of a product or reducing its "risk of danger" would require redesigning the drug." *Id.* at 2475. It held design defect claims are preempted because legally a drug may not be changed without FDA's prior approval. *Id.*

Like *Mensing*, Bartlett involved a generic drug, but the holdings in both cases apply equally to drugs approved under an ANDA or an NDA. Following *Levine*, *Mensing*, and *Bartlett*, it is clear that "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Mensing*, 465 U.S. at 623-24.

3. Design Defect Claims Directed at Pharmaceutical Products Are Preempted By Federal Law

Plaintiffs' design defect claims are preempted by federal law. "Once a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'" *Bartlett*, 133 S. Ct. at 2471 (citation omitted) (quoting 21 C.F.R. § 314.70(b)(2)(i)). A design defect theory would require defendants to redesign ParaGard®. That is precisely the kind of impossibility that led the

Supreme Court and other courts to find preemption. As the Supreme Court definitively stated in *Bartlett*, "we hold that state-law design-defect claims like New Hampshire's that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling." *Id*. Importantly, a hypothetical supposition that the "FDA may approve an alteration does not negate the present impossibility." *Barcal v. EMD Serono, Inc.*, 2016 WL 1086028, at *4 (N.D. Ala. 2016).

In *Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1139-1140 (8th Cir. 2014), the Eighth Circuit Court of Appeals applied *Bartlett* and held the plaintiff's claims were preempted. In *Brinkley*, the plaintiff alleged she developed a neurological disorder as a result of taking defendant's product long-term. *Id.* at 1136. In affirming the district court's dismissal of the plaintiff's design defect claim, the Eighth Circuit held that federal law preempts state law claims that would require the manufacturer to redesign its drug. *Id.* at 1139-40. The court noted that "[s]ince *Bartlett*, there is a growing consensus in the federal circuit courts that the preemption analysis in *Mensing* and *Bartlett* proves fatal to state law claims like [the plaintiff's]." *Id.* (citations omitted).

Similarly, in *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281 (6th Cir. 2015), the United States Court of Appeals for the Sixth Circuit, applying *Bartlett*, found the plaintiff's design defect claim preempted. The plaintiff in *Yates* had a stroke after using a birth control patch and sued the brand-name manufacturers for various claims under New York law, including defective design. *Id*. at 287-88. The plaintiff contended, even after the FDA approved the medication, that the defendant manufacturers had a duty to change the design of the medication once they discovered that it was unreasonably dangerous. *Id*. at 297-98. As framed by the Sixth

Circuit, the issue in *Yates* was whether the defendants could have complied with their alleged duty under New York law to change the product design post-approval, while simultaneously complying with federal law." *Id*. at 294. After careful analysis, the Sixth Circuit rejected the plaintiff's arguments and held that federal law expressly prohibited the defendants from complying with New York's design defect law. *Id*. at 297-300.

The Sixth Circuit held that the plaintiff's "design defect claim is clearly preempted by federal law." *Id*. at 298. The court reasoned that "FDA regulations provide that once a drug, whether generic or brand-name, is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the specifications provided in the approved application.'" *Id*. (quoting 21 C.F.R. § 314.70(b)(2)(i)). The court was "convinced" and thought that it was "clear" that the plaintiff's suggested design change—reducing the dosage of estrogen in the medication—amounted to a "major change" in the medication. *Id*. The court thus concluded that "to the extent [the plaintiff] argues that defendants should have altered the formulation of [the medication] after the FDA had approved the patch," the claim clearly was preempted as "federal law prohibited defendants from decreasing the dosage of estrogen post-approval." *Id*. at 298-99 (emphasis added).

Other courts agree. For example, in *Barcal*, the plaintiff alleged that her mother's use of the fertility medication Serophene caused her to be born with a severe cardiac birth defect. *Barcal*, 2016 WL 1086028, at *1. The court held that the plaintiff's design defect claim under state law was preempted by federal law. *Id*. at *3. The court reasoned that the state law claim "would essentially require [the defendant] to redesign Serophene." *Id*. at *4. "This is precisely the kind of impossibility in which the Supreme Court has found preemption." *Id*. FDA-

approved medicines "cannot be altered without the FDA's prior permission, rendering compliance with both state and federal law impossible." *Id.*; *see also Utts v. Bristol-Myers Squibb Co.*, --- F. Supp. 3d ---, 2016 WL 7429449, *11-12 (S.D.N.Y. Dec. 23, 2016) (dismissing design defect claim as preempted); *Fleming v. Janssen Pharm., Inc.*, 2016 WL 3180299, *4-5 (W.D. Tenn. 2016) (same); *Rheinfrank v. Abbott Labs., Inc.*, 137 F. Supp. 3d 1035, 1040-41 (S.D. Ohio 2015) (same); *Shah v. Forest Laboratories, Inc.*, 2015 WL 3396813 (N.D. Ill. May 26, 2015)(same); *Booker v. Johnson & Johnson*, 2014 WL 5113305 (N.D. Ohio Oct. 10, 2014) (same); *Amos v. Biogen IDEC, Inc.*, 2014 WL 2882104, *3 (W.D.N.Y. Oct. 10, 2014) (same).

As in those cases, a design change to ParaGard® would require FDA-approval. Thus, it is impossible for defendants to redesign the product without violating federal regulations. Accordingly, any design defect claim is preempted by federal law.

4. Plaintiff's Failure-to-Warn Claims Are Preempted as Plaintiff Does Not Identify any "Newly Acquired Information" that Would Warrant or Support a Label Change

Like any design defect claim, plaintiff's failure-to-warn claims are preempted.[2] The United States Court of Appeals for the First Circuit applied the Supreme Court's preemption trilogy in *In re: Celexa and Lexapro Marketing and Sales Practices Litigation*, 779 F.3d 34 (1st Cir. 2015), a case involving NDA pharmaceuticals. In its decision, the First Circuit acknowledged that a state-law claim is preempted where the company cannot act independently under federal law to do what state law requires. *Id*. at 44 (*citing Mensing*, 564 U.S. at 623-24;

[2] Plaintiff's Third Cause of Action is titled "Breach of Express" Warranty. (*See* Complaint, p. 13.) In reality, although plaintiff includes the necessary express warranty buzz words, that cause of action is no more than a differently-titled failure-to-warn claim as evidenced by plaintiff's allegation that defendants did not "accurately warn" of purported "serious side effects." (*Id.*, ¶63.) As such, the preemption analysis applies equally to that cause of action. The same is true of plaintiff's fraudulent and negligent misrepresentation causes of action. (*Id.*, ¶78 (alleging defendants knew or should have known ParaGard "lacked adequate and/or sufficient warnings"); ¶86 (defendants "misrepresented ParaGard's high risk of unreasonable, dangerous side effects"). The substitution of the buzz word "misrepresentation" for "inadequate warning" in her misrepresentation claim is a distinction without a difference. The gravamen of the claim remains one of purportedly failing to warn.

Bartlett, 133 S. Ct. 2466). The court recognized that an NDA holder can use FDA's CBE supplement process to change product labeling only where "newly acquired information" becomes available supporting certain changes to certain sections of product labeling. *Celexa*, 779 F.3d at 37; see also 21 C.F.R. §314.70(c)(6). As a result, the court concluded that a plaintiff must allege, in the first instance, what "newly acquired information" warrants the label change the plaintiff advocates. The court ruled that the plaintiffs did not overcome the preemptive effect of federal law because the plaintiffs did not allege any "newly acquired information" existed that would have supported an independent label change the company could have made. *Id*. at 42-43. In other words, the "clear evidence" standard is never reached if plaintiff does not identify any "newly acquired information" that would have supported submission of a CBE supplement.

Plaintiff has not identified in the Complaint any "newly acquired information" that would have warranted a change in the ParaGard® package insert after September 1, 2005, when FDA approved the ParaGard® labeling following a thorough review by FDA and revisions to both its content and format and before plaintiff's ParaGard® was placed in 2010. Without newly acquired information that scientifically supports a change, the ParaGard® label could be changed only with "[FDA's] special permission and assistance," i.e., through submission of a PAS. As a result, plaintiff' warning claims are preempted.

Changes using a CBE supplement are limited to those based on "newly acquired information" that supports a change to add or strengthen a contraindication, warning, precaution, adverse reaction; a statement about drug abuse, dependence, or overdosage; an instruction about dosage and administration that is intended to increase the safe use of the drug product; or that would delete false, misleading, or unsupported indications for use or claims for effectiveness. *See* 21 C.F.R. §314.70(c)(6)(iii); *see also Seufert v. Merck Sharp & Dohme Corp.,* 187 F. Supp.

3d 1163, 1176 (S.D. Cal. 2016) (acknowledging pharmaceutical manufacturer can use CBE to make label change "only when a submission is supported by sufficient scientific data"). Without any "newly acquired information" to support submission of a CBE, any change to a pharmaceutical product's label must be accomplished through FDA's prior approval process (unless the change falls within the categories FDA delineated as reportable in the company's annual report).

Plaintiff's Complaint, however, is bereft of allegations that any new safety information existed to support a label change to ParaGard®'s package insert. Plaintiff must, but has not and cannot, plead "newly acquired information" by defendants between September 1, 2005, and plaintiff's January 11, 2010, ParaGard® placement that would have supported submission of a CBE to make any change to the ParaGard® package insert. As a result, any claim premised on a failure to make a change to ParaGard®'s package insert is preempted and defendants are entitled to judgment as a matter of law.

D. PLAINTIFF'S FRAUDULENT MISREPRESENTATION CLAIM IS NOT PLED WITH THE REQUISITE SPECIFICITY

Plaintiff's fraudulent misrepresentation claim is subject to Federal Rule of Civil Procedure 9(b)'s heightened pleading standards for fraud-based claims, and must specifically allege "such facts as the time, place, and content of the defendant's false representations, as well as the details of the defendant's fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result." *U.S. ex rel., Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552 (8th Cir. 2006); *see also Brooks v. Blue Cross and Blue Shield of Fla., Inc.*, 116 F.3d 1364, 1380-81 (11th Cir. 1997) (noting fraud-based claim must specifically allege "(1) the precise statements, documents, or misrepresentations made; (2) the time, place, and person responsible for the statement; (3) the content and manner in which these statements mislead the

Plaintiffs'; and (4) what the defendants gained by the alleged fraud."). Stated differently, plaintiff must identify the "who, what, where, and how" of the alleged fraud. *Id.*

Plaintiff's claims do not. Fundamentally, nowhere in the Complaint does plaintiff identify any representation of fact, let alone a representation of fact that is false.[3] Under the "fraudulent misrepresentation count," plaintiff plays games with the ParaGard® label, making up language that is nowhere to be found in the label and inferring statements that simply do not exist. For example, a statement that ParaGard® is "safe" (*see* Complaint, ¶72) appears nowhere in the ParaGard® label – and plaintiff points to no such language in the label (nor can she). In fact, as plaintiff acknowledges, the ParaGard® label warned of various risks, including perforation, embedment, and breakage. Plaintiff's allegation that defendants made a false representation regarding ParaGard® is entitled to no deference or presumption of truth, and does not satisfy the plausibility mandate set forth in *Twombly* and *Iqbal*, or the heightened Rule 9 pleading standards.

IV. CONCLUSION

Plaintiff's claims against defendants are inadequately pled. Further, design defect and failure-to-warn claims are preempted by federal law. Accordingly, defendants' motion for judgment on the pleadings should be granted.

Respectfully submitted,

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[3] Notably, the word "fraud" does not appear in plaintiff's description of her claims in the Rule 26(f) report.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing has been served, via the Court's ECF system, this 10th day of July, 2017, upon:

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